

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL 2327</b>
<b>THIS DOCUMENT RELATES TO: WAVE 1 CASES ON ATTACHED EXHIBIT A</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**REPLY MEMORANDUM IN FURTHER SUPPORT OF PLAINTIFFS' MOTION  
TO EXCLUDE CERTAIN OPINIONS OF DR. STANLEY ZASLAU**

In further support of their Motion to exclude certain opinions and testimony of Defendants' Urology and Femal Pelvic Medicine and Reconstructive Surgery expert, Stanley Zaslau, M.D., MBA, FACS ("Dr. Zaslau"), Plaintiffs state as follows.

**ARGUMENT**

**I. Dr. Zaslau's particle loss and fraying opinions are still not reliable**

Plaintiffs argued that there is no scientific reliability to Dr. Zaslau's claim that he has not personally observed mesh particle loss or fraying—the classic "I have not seen it, so it does not happen" testimony—and, therefore, there can be no scientific reliability to his claim that if it does occur is must not be clinically significant. Mot. at 3-6. In response, Ethicon asserts:

Dr. Zaslau's statement *does not suggest* that the absence of degraded particles in meshes Dr. Zaslau has seen is evidence that such particles *are absent in all cases*. Instead, his statement is just part of his basis for his opinion that there is no clinically significant difference between machine-cut and laser-cut mesh.

Def's Brf. at 2. First, if Dr. Zaslau does not, and cannot, opine on the occurrence (or lack thereof) of particle loss and fraying of mesh, generally, then his untested, unrecorded, and

unverified “observations” from his own surgeries are of no use to the jury. Moreover, if Dr. Zaslau does not contest that particle loss or fraying may occur in other cases—just not in his cases—that actually further undermines his opinion that, if it does occur, it is not clinically significant. Indeed, if Dr. Zaslau cannot rule it out in other cases, and has no actual knowledge of the degradation or its effects in those cases, how can he claim that it is not clinically significant? He cannot. In other words, Dr. Zaslau’s testimony is even more unreliable and irrelevant than the “I have not seen it, so it does not occur” testimony that this Court has previously excluded.<sup>1</sup> Here, Dr. Zaslau essentially wants to tell the jury: “I have not seen it. I am not actually sure whether or not it occurs. But if it does occur, I *suspect* that it is not serious.”

Ethicon also argues that Dr. Zaslau’s opinions are based upon “a review of peer-reviewed medical literature” and that “the literature plainly recognizes that some foreign-body responses are subclinical.” Def’s Brf. at 2-3. But Dr. Zaslau did not claim as much at his deposition, and the literature that Ethicon points to in its brief was not even included on Dr. Zaslau’s reliance list. *See* Ex. A, Zaslau Reliance List. In other words, Dr. Zaslau, himself, did not rely on scientific literature to support his opinions—Ethicon has just tried to scrounge some up in response to Plaintiffs’ *Daubert* challenge. But in the end, neither Dr. Zaslau nor Ethicon has pointed to any literature that was part of Dr. Zaslau’s purported “literature review” that would support his conclusions.<sup>2</sup> And it is not just that “Plaintiffs and their experts [] disagree with Dr. Zaslau’s conclusions” as Ethicon claims, it is that he has admitted that the scientific literature—and Ethicon itself—disagrees with his unsupported opinions. Mot. at Ex. C, 104:3-10; 105:3-106:5.

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<sup>1</sup> *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 583-85 (S.D. W. Va. 2014)).

<sup>2</sup> The article cited by Ethicon does not deal with foreign body response do to polypropylene particle loss.

Finally, Ethicon simply ignores Plaintiffs’ argument that Dr. Zaslau admitted to not even knowing that there was a difference between laser-cut and mechanical-cut mesh prior to this litigation. Mem. at 4-5. Simply put, Dr. Zaslau is not capable of providing useful or reliable expert testimony on this issue.

## **II. Ethicon’s response does not support or justify Dr. Zaslau’s “sheath opinion”**

Ethicon argues that Dr. Zaslau’s opinion that mechanical-cut mesh will not rope or curl when properly implanted using the accompanying plastic sheath is based “on reliable *ex vivo* experiments and *in vivo* observations.” Def’s Brf. at 4-5.

First, to the extent Ethicon claims that Dr. Zaslau has conducted “*ex vivo* experiments” on the mesh, that “testing” should be excluded as unreliable and unscientific. Dr. Zaslau has not provided any information or documentation relating to these “experiments”—*e.g.* no written protocol; no testing parameters; no controls; no information on sample size; no indication of the specific mesh product or pull-force used, or conditions present during testing; no record of the data or results; no published findings; and no discussion of the scientific standards followed. Dr. Zaslau simply claims to have, at some point in the past, “pull[ed] on” some mesh with and without a sheath. *See* Def’s Brf. at 4. There is absolutely nothing scientific or reliable about what Dr. Zaslau claims to have done. To call these “experiments” is an affront to the scientific method. And contrary to Ethicon’s assertion to the contrary, these so called experiments cannot be verified, tested, or repeated by anyone. Def’s Brf. at 5. As such, they cannot stand as a basis for reliable expert testimony. Indeed, this Court has previously excluded much more detailed, verifiable, and scientific testing than this. *E.g. Mathison v. Boston Sci. Corp.*, NO. 2:13-cv-05851, 2015 U.S. Dist. LEXIS 59047 at \*68-69 (S.D. W. Va. May 6, 2015) (excluding testing of Dr. Dunn).

Moreover, Ethicon makes no arguments in support of its claim that Dr. Zaslau relied on “*in vivo* observations.” As Plaintiffs point out in their memorandum, Dr. Zaslau admits that these opinions are contradicted by the scientific literature, and he cannot provide any support for them other than what he claims to have “seen.” Mot. at 6-7. Plaintiffs should not be required to just “take [his] word for it.” Mot. at Ex. C, 102:1-103:5.

### **III. Dr. Zaslau should be precluded from testifying that polypropylene does not degrade *in vivo***

Ethicon claims that Plaintiffs rely on “out-of-context quotes” from Dr. Zaslau’s deposition. Def’s Brf. at 5. But Ethicon does not follow-up that assertion by providing an explanation or examples of how the quoted testimony was taken out-of-context. Instead, it just restates Dr. Zaslau’s opinion that if degradation does occur, it is not clinically significant. *Id.* at 5-6. There was no confusion about what Dr. Zaslau seeks to tell the jury. Through their Motion, Plaintiffs contested the reliability of that testimony and Dr. Zaslau’s qualification to render it.

There is nothing “out-of-context” about the testimony that Plaintiffs quoted in their memorandum. Dr. Zaslau admitted that he did not, and would not, consider the scientific literature or other evidence relating to degradation. Mot. at Ex. C, 124:16-125:3; *see also* 126:15-24; 127:21-24; 160:20-23. Instead, Dr. Zaslau chose to ignore that relevant evidence.<sup>3</sup> For this reason alone, Dr. Zaslau cannot offer the opinion that “there are no reliable scientific studies evaluating TVT or TVT-O that have demonstrated any clinical significance to alleged...degradation.” Def’s Brf. at 6

Ethicon’s reliance on this Court’s ruling with regard to Dr. Pramudji in *Huskey* is not conclusive on this issue. First, to the extent there is a conflict between that ruling and the

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<sup>3</sup> *See Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 U.S. Dist. LEXIS 137189 at \*70 (S.D. W. Va. Sept. 29, 2014).

Court's ruling in *Tyree*—where the Court rightly opined that the “absence of evidence is not evidence of absence”—the Court's more recent ruling in *Tyree* should apply. *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 583-85 (S.D. W. Va. 2014)). Moreover, the Court's opinion in *Huskey* only permitted Dr. Pramudji to testify “whether she has observed mesh degradation in her clinical practice.” *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 726-727 (S.D. W. Va. 2014). That is a completely different—and much more benign—opinion than Dr. Zaslau's claims that “degradation is not clinically significant” and that “there is no causal link” between degradation and *any* complication. *See* Def's Brf. at 5. Regardless of what he claims to have observed, he has absolutely no support for those opinions.

**IV. Dr. Zaslau's opinion that the TVT is not associated with chronic or long term pain is completely unsupported, and therefore, unreliable**

As Plaintiffs pointed out in their memorandum, Dr. Zaslau could not provide a single piece of support for his proffered testimony that “[v]ery few people who have had a carefully-implanted device will have *long-term* pain.” Mot. at Ex. C, 72:10-12; 72:22-73:20; *see also* 74:5-75:19. Ethicon claims that Plaintiff is “wrong”—citing to the fact that Dr. Zaslau made reference to the Tommaselli meta-analysis. Def's Brf. at 7 (*citing* Mot. at Ex. C, 74:5-22). But Dr. Zaslau himself acknowledged that the article does not qualify as a “long-term” study. This is not simply a situation where Dr. Zaslau had an “inability to recall” something at the time of his deposition, as Ethicon seeks to portray it. *Id.* Dr. Zaslau was given, and took, the opportunity to review his reliance materials. After which, he admitted that he “can't think of or find one that specifically refers to that for the long-term.” Mot. at Ex. C. 72:22-73:20. And tellingly, Ethicon has not specifically cited to one long-term study supporting Dr. Zaslau's “long-term pain” opinions in its response brief. Def's Brf. at 7-8 (*citing* Dr. Zaslau's Reliance List as “*see*

*generally*”). Again, Dr. Zaslau’s opinions amount to nothing more than the type of “unsupported speculation” that must be excluded under *Daubert*.<sup>4</sup>

Dated: May 16, 2016

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<sup>4</sup> *Brown*, 1997 U.S. App. LEXIS 23559 at \*3 (the expert’s testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); *see also Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

**CERTIFICATE OF SERVICE**

I hereby certify that on May 16, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

s/ Edward A. Wallace